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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,323	12/20/2004	Masazumi Nishikawa	263192US0PCT	3573
22850	7590	12/10/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
MERCIER, MELISSA S				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
12/10/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/517,323

Applicant(s)

NISHIKAWA ET AL.

Examiner

MELISSA S. MERCIER

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 22, 25-36 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 22, 25-36 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on September 8, 2008 is acknowledged. Claims 18-19, 22, 25-36, and 39-41 remain pending in this application. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-41 recite the limitation "the composition of claim 18" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 18 is drawn to a method and not a composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-19, 22, 25-36, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (US Patent 5,602,183) in view of Norwegian Shark Oil product information sheet.

Martin discloses therapeutic dermatological wound healing compositions. The composition comprises:

- a. pyruvate
- b. an antioxidant
- c. a mixture of saturated and unsaturated fatty acids (abstract).

The composition can be used to treat erythema caused by diapers (column 6, lines 35-53), and protecting the skin from UV light damage (column 21, lines 48-49).

The mixture of saturated and unsaturated fatty acids can be marine oil, especially shark liver oil (column 14, lines 14-15). Applicant's disclosure on page 8 discloses a method for extracting diacylglycerol ether, triglycerides, and squalene from shark liver oil. Therefore, it is the examiners position that the use of shark liver oil would inherently possess the ether compound, as well as triglycerides and squalene, in the amounts recited in claim 39, and thus the administration of shark liver oil meets the limitations of the instant claims.

Regarding claims 22-29, the composition can also be in the form of a topical product or ingestible product (column 21, lines 25-28). Examples of oral compositions include toffees, nougats, suspensions, tablets, and gums (column 23, lines 48-52).

Regarding claim 31, a variety of traditional ingredients can be added including buffers, preservatives, tonicity adjusting agents, antioxidants, polymers and excipient (column 23, lines 59-63).

Regarding claim 40-41, the claim limitations are considered to be product by process limitations. Since the prior art discloses the same product used for the same purpose, the process from which it is made does not hold patentable weight. Applicant's attention is directed to MPEP 2113, which discloses, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Burden is shifted to Applicant to provide a patentable distinction between the administration of the shark liver oils of the prior art and that of the instant claims.

Martin does not particularly disclose skin cancer induced by UV light, formation of pigmented spots induced by UV light, formation of freckles induced by UV light, formation of wrinkles induced by UV light, formation of verrucae induced by UV light, and formation of erythema induced by UV light as recited in claims 32-36. Martin additionally does not disclose the daily dosage of the composition.

Regarding the dosages recited in claims 19, 25-26, 30, it is the position of the examiner that one of ordinary skill in this art would have the knowledge for determining

optimum dosing schedules of the composition in order to obtain the optimum therapeutic effect of the compound. Shark liver oil is routinely dosed in 1000mg capsules, as evidenced by the Norwegian Shark Oil product information sheet attached to this office action.

Regarding the specific conditions of claims 32-36, It would have been obvious to one of ordinary skill in the art to have used the composition of Martin for the treatment of UV light induced skin damage since Martin discloses wounds are internal or external bodily injuries caused by physical or thermal means (the examiner has interpreted thermal to include UV light). It is additionally disclosed Martins wound healing compositions prevent and reduce injury to mammalian cells while increasing the resuscitation rate of injured mammalian cells. Cells treated with the therapeutic wound healing compositions of Martin show decreased levels of hydrogen peroxide production, increased resistance to cytotoxic agents, increased rates of proliferation, and increased viability. Cellular cultures containing the therapeutic wound healing compositions showed enhanced differentiation and proliferation over control cultures and rapidly formed attachments or tight junctions between the cells to form an epidermal sheet. Wounded mammals treated with the therapeutic wound healing compositions show significantly improved wound closing and healing over untreated mammals and mammals treated with conventional healing compositions (column 8, lines 19-35). Since the prior art discloses the composition can be used to treat UV induced skin damage, it would have been obvious to one of ordinary skill in the art to attempt treatment utilizing

the composition for the instantly claimed disorders since they all arise from the same origin.

Conclusion

Due to the new grounds of rejection presented in this office action, this **action is made Non-Final**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615